K 100937

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510(k) SUMMARY

(As required by 21.CFR.807.87)

DEC 21 2010

A. Introduction: According to the requirements of 21 CFR.807.92, the following information provides data needed to understand the basis for determining substantial equivalence.

B. 510(k) Number is: K100937

C. Type of 510(k): Traditional

D. Purpose for Submission: New submission for the Data Management Software which is an accessory application for glucose meters.

E. Submitted By:
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F. Contact Person:
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G. Device Name:
Trade name: **PC care™** Blood Glucose Data Management Software
Common Name: Data Management Software
Classification Name: Unclassified (accessory to a BGM system)

H. Type of Test: PC care™ Blood Glucose Data Management Software is a software medical device that interfaces with the i-SENS blood glucose monitoring systems using the special USB cable (It is activated with the PC care™ program only).

1. System Description:

1) Device Description:

The PC care™ Blood Glucose Data Management Software is an optional data management software for use only with the i-SENS Blood Glucose Meters. The PC care™ Blood Glucose Data Management Software allows the transfer of data from the i-SENS Blood Glucose Meters to a personal computer for enhanced data management using graphic displays and analysis tools of the device. Various graphic analysis tools in this software help users of i-SENS BGM system easily analyze the trends and changes in their blood glucose.

2) Operation principle:

The PC care™ Blood Glucose Data Management Software downloads all blood glucose test results along with their measurement dates and times from the i-SENS Blood Glucose Meters through the USB port connected to the PC with the special cable. The PC care™ Blood Glucose Data Management Software operates under a Microsoft Windows Operating System and provides reports containing variety of graphs and statistics based on User-selectable data interval and blood glucose target ranges.

3) System Requirements:

· CPU: 300 MHz Intel Pentium 2 or equivalent
· RAM: 128 MB or higher
· Minimum free hard disk space: 60 MB
· Windows 95, Windows 98, Windows ME, Windows 2000, Windows XP, Windows Vista (only 32bit), and Windows 7 (only 32bit).
· USB port
· PC care™ USB cable
· Mouse / Keyboard
· Video monitor and adapter with at least 1024x768 pixel screen resolution and 256 colors
· CD-ROM drive
· Printer (optional)

J. Regulation Information:

1) Regulation section:

· 21 CFR Sec. 862.1345 - Glucose test system.

· 21 CFR Sec. 862.2100 - Calculator/data processing module for clinical use.

2) Classification: Class II and I, respectively

3) Product code:

· NBW - System, Test, Blood Glucose, Over The Counter

· JQP - Calculator/Data Processing Module, For Clinical Use

4) Panel: 75, Chemistry

K. Intended Use:

The PC care™ Blood Glucose Data Management Software is PC-based software intended for use in the home and professional settings to help people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results for an effective diabetes management program. The PC care™ Blood Glucose Data Management Software connects to an i-SENS blood glucose meter, which comes with a PC care USB cable. The PC care™ Blood Glucose Data Management Software allows the user to download Blood glucose readings automatically from the meter to the PC.

L. Substantial Equivalence Information:

We believe substantial equivalence to the Zero-Click™ Data Management System previously submitted by AgaMatrix, Inc. and subsequently cleared by FDA.

1) Predicate Device Name(s): Zero-Click™ Data Management System

2) Device Company: AgaMatrix, Inc.

3) Predicate 510(k) Number(s) : k062434

M. Comparison with Predicate Device (k062434):

The glucose measurement test principle:
same as Zero-Click™ Data Management System
Intended Use:
same as Zero-Click™ Data Management System

1) Similarities

Item	PC care™ Blood Glucose Data Management Software *(Device)*	Zero-Click™ Data Management System *(Predicate Device)*
	About User	
Intended Use	The PC care™ Blood Glucose Data Management Software is PC-based software intended for use in the home and professional settings to help people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results for an effective diabetes management program. The PC care™ Blood Glucose Data Management Software connects to an i-SENS blood glucose meter, which comes with a PC care USB cable. The PC care™ Blood Glucose Data Management Software allows the user to download Blood glucose readings automatically from the meter to the PC with or without clicking a button.	The Zero-Click™ Data Management System is intended for use in the home and professional settings to aid people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results to support an effective diabetes management program. It is an optional data management software accessory for use with the AgaMatrix's Liberty™ Blood Glucose Monitoring System. The Zero-Click™ Data Management System allows users to download Blood glucose reading automatically from the meter to the PC without clicking a button.
Software use indications	Single or Multiple user settings	Single or Multiple user settings
	About Installation	
Installation of Program	Installed Using CD	Installed Using CD
Ability to uninstall DMS program	Yes	Yes
Computer System Requirements	CPU: Minimum 300MHz Intel Pentium 2 or equivalent	CPU: Minimum 700MHz, Intel Pentium processor
	RAM: 128 MB or higher	RAM: Minimum 128 MB

Item	PC care™ Blood Glucose Data Management Software *(Device)*	Zero-Click™ Data Management System *(Predicate Device)*
	Minimum free hard disk space: 60 MB	Hard drive space: 60 MB Minimum (100 MB Recommended)
	Windows 95, Windows 98, Windo ws ME, Windows 2000, Windows XP, Windows Vista (only 32bit), and Windows 7 (only 32bit).	Windows XP and Vista (32 bit)
	USB port	USB port
	PC care™ USB cable	Zero-Click™ Data Cable
	Mouse and keyboard	Mouse and keyboard
	Video monitor and adapter with at least 1024x768 pixel screen resolution and 256 colors	Monitor: Minimum 1024x768 resolution
	CD-ROM drive	CD-ROM drive
	Printer (optional)	Printer (optional)
Technical support	Yes	Yes
About Transmission		
Capable of uploading data from various devices	Software driver must be installed on PC	Software driver must be installed on PC
Cable availability	USB cable	USB cable
Auto-detect COM port	Yes	Yes
About Operation		
Ability to access DMS program via icon or explorer	Yes	Yes
Viewing the Owner's Manual	Click the Help menu in the program or personally open the manual file in the installing CD.	Accessed via Help on toolbar or F1 on computer
Ability to clear meter results in memory	No	No

Item	PC care™ Blood Glucose Data Management Software *(Device)*	Zero-Click™ Data Management System *(Predicate Device)*
Indication for primary test method	Not available	Not available
Ability to email report from PC directly from program	Yes	Yes
Time Block	Before/After Breakfast, Before/After Lunch, Before/After Dinner, Evening/Sleep Night	Before/After Breakfast, Before/After Lunch, Before/After Dinner, Night
	About Personal Settings	
Units of measure automatically set by country in setup installation	No	No
Ability to personalize target ranges	Yes	Yes
Ability to set default target range by diabetes type (Type I, Type II Gestational, etc.)	No	No
Default glucose target ranges available	Yes	Yes
Ability to enter hypoglycemic range	Yes	Yes
Ability to set default favorite report	Yes	Yes
Ability to enter insulin regiment	No	No
Change meter audio cues	No	No
	About Report	

Item	PC care™ Blood Glucose Data Management Software *(Device)*	Zero-Click™ Data Management System *(Predicate Device)*
Ability to print report	Yes	Yes
Result type display	No	No
Ability to view results and sort without generating report	No	No
About Modifying Results		
Downloaded results cannot be edited or deleted	Yes	Yes
Manual data Entry	allowed	allowed
Ability to input additional information on patient and downloaded results	Yes – Health Profile, comment	Yes – Meal tag, Comments
Deleting Results	Only Manual entry results may be deleted	Only Manual entry results may be deleted
Ability to modify meter average results	Yes, 14, 30, 60, 90 days or custom	Yes, Today, 7, 14, 30, 60, 90 days or custom
Ability to view control results	No	No
Ability to show cholesterol results/select units of measure	No	No
Ability to enter test site for manual result entry	No	No
Ability to input additional information on manual result	Yes – comment	Yes – Meal tag, Comments
About Patient and Therapy Management		
Required information	No	No

Item	PC care™ Blood Glucose Data Management Software *(Device)*	Zero-Click™ Data Management System *(Predicate Device)*
on patient entry		
Customizable schedule	Yes	Yes
Search patient capability	No	No
Search for specific patient in multiple (clinic) user function	No	No

2) Differences

Item	PC care™ Blood Glucose Data Management Software *(Device)*	Zero-Click™ Data Management System *(Predicate Device)*
About Transmission		
Function that monitors the communication status	Yes	No
About Operation		
Ability to set meter clock to a specific date and time	No	Yes
Copy saved database back to active DMS database	No	Yes
Copy database to separate file	No	Yes
About Personal Settings		
Units of measure display	Choice of mmol/L or mg/dL	Automatically selected based on unit already set up in meter
Ability to change date format	No	Yes (M-d-yy or d-M-yy)

Item	PC care™ Blood Glucose Data Management Software *(Device)*	Zero-Click™ Data Management System *(Predicate Device)*
Ability to synchronize meter clock to PC upon download	No	Yes
Ability to default to manufacturer settings (mealtime slots, target glucose ranges, etc.)	No	Yes
Ability to display12 or 24 hour clock format	No	Yes
About Report		
Report Types	Trend Graph, Average Analysis, Histogram, Target Analysis, Logbook, Statistics, Period Comparison Graph	Summary, Log Book, Target Analysis, Glucose Trend, Histogram, Average/Spread, Statistics
When printing Report, check if select function for the color/black and white mode exists	Yes	No
About Modifying Results		
Ability to specify complications associated with diabetes by patient	Yes	No
Specifying/Entering medications/insulin	Yes, up to 3 different insulin type	No
About Patient and Therapy Management		
Diabetes control	Yes – Insulin list, Medication list, Diet/Exercise options	No
Doctor information	Yes - One doctor name may be entered	No

Item	PC care™ Blood Glucose Data Management Software *(Device)*	Zero-Click™ Data Management System *(Predicate Device)*
Deleting Patients and all accompanying records	No	Yes
Insurance information	Yes - One insurance number may be entered	No
Hospital Information	Yes - One hospital name may be entered	No
Diabetes Educator information	Yes - One diabetes Counselor may be entered	No
Ability to input additional information on patient	Yes – Date of diagnosis, Insulin Initial Date/Dosage Method, Oral Medication Initial Date, Diet, Exercise, Working/Non-Working day	No

N. Modifications: Among various functions, only simple and essential functions have been selected and incorporated for user convenience.

O. Standard/Guidance Document Referenced (if applicable):
1) FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
2) Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203)
3) ISO 15197: 2003 In vitro diagnostic test system

P. Test Principle: Not Applicable

Q. Validation Activities: The test reports in this table are included in this submission, and can be found under the Section Numbers below.

- SV-05-Q. Software Validation Report (Question)
- SV-05-A. Software Validation Report (Answer)
- TR-EI-025-Starting Up Test
- TR-EI-026-Printing Reports Test
- TR-EI-027-Email Test
- TR-EI-028- CareSens N Download Readings Test
- TR-EI-029-Manual Entry Test
- TR-EI-030-User Profile Test
- TR-EI-031-Reports Test
- TR-EI-060-Install Test
- TR-EI-085-CareSens Communication Protocol
- TR-EI-113-CareSens II Download Readings Test

R. Proposed Labeling: The labeling is sufficient and it satisfies the requirement of 21 CFR Part 809.10.

S. Conclusion: **The submitted information in this premarket notification is complete and supports a substantial equivalence decision.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

DEC 21 2010

I-Sens, Inc.
c/o Hyun Oh
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Seoul, 139-845
KS - REPUBLIC OF KOREA

Re: k100937
Trade/Device Name: PC care Blood Glucose Data Management Software
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II
Product Code: NBW, JQP
Dated: November 19, 2010
Received: November 19, 2010

Dear: Dr. Oh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K100937

Device Name: The PC care™ Blood Glucose Data Management Software

Indications for Use:

The PC care™ Blood Glucose Data Management Software is PC-based software intended for use in the home and professional settings to help people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results for an effective diabetes management program. The PC care™ Blood Glucose Data Management Software connects to an i-SENS blood glucose meter, which comes with a PC care USB cable. The PC care™ Blood Glucose Data Management Software allows the user to download Blood glucose readings automatically from the meter to the PC.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K100937